

## **REMARKS**

### **I. Status of Claims**

Claims 1-17 are pending in the application. Claims 2, 14, and 15 are withdrawn by the examiner from consideration as drawn to non-elected inventions. Claims 1 and 16 in part, 3-13 and 17, which are drawn to a method of treatment or prevention of a disorder in a mammal comprising administering to said mammal an amount of a human anti-IGF-IR antibody wherein the disorder is multiple myeloma, are examined to the extent the agent species is “analgesic”, the vaccine species is “autologous tumor vaccines”, the anti-proliferative species is “PDGFR inhibitors”, the antibody species is “2.13.2”, and the VH gene species is “VH DP-47” and the VL gene species is “A30”. Claims 1, 3-13, 16, and 17 are rejected.

By this amendment applicants have cancelled claims 9, 11, and 13, and deleted the term “prevention” in claim 1. After the entry of this amendment claims 1- 8, 10, 12, 14 -17 are pending in the application.

The amendment does not add new matter to the application.

### **II. General Remarks**

Applicants have noted the Examiner’s remarks regarding Applicants’ response to the Election/Restrictions requirement issued in the previous Office action, and the Examiner’s remark that deposit of antibody 2.13.2 is not required.

### **III. Claim Rejections - 35 U.S.C. §112, Second Paragraph**

Claims 9 and 13 are rejected under 35 U.S.C. §112, second paragraph, allegedly as being indefinite. The basis of the rejection relates to the recitation of the terms “gene” (claims 9 and 13) and “derived” (claim 13). Without conceding the correctness of the rejection and for the purpose of expediting the allowance of the application, Applicants have cancelled both claims 9 and 13, which renders the rejection moot.

### **IV. Claim Rejections - 35 U.S.C. §112, First Paragraph**

Claims 9 and 13 are rejected under 35 U.S.C. §112, first paragraph, allegedly as failing to comply with written description requirement. The basis of the rejection relates to the recitation of “gene”. Without conceding the correctness of the rejection and for the purpose of expediting

the allowance of the application, Applicants have cancelled both claims 9 and 13, which renders the rejection moot.

**V. Claim Rejections - 35 U.S.C. §112, First Paragraph**

Claims 1, 3-13, and 17 are rejected under 35 U.S.C. §112, first paragraph, allegedly for lack of enablement with respect to recited a method of “prevention” of a disorder. Without conceding the correctness of the rejection and for the purpose of expediting the allowance of the application, Applicants by this amendment have deleted the reference to “prevention” of a disorder, which, as a result, overcomes the rejection.

Claim 11 is rejected on an additional basis that the specification does not teach IGF-IR antibodies that contain substitutions, additions or deletions within the CDRs. Without conceding the correctness of the rejection and for the purpose of expediting the allowance of the application, Applicants by this amendment have cancelled claim 11, rendering the rejection moot.

**VI. Claim Rejection under 35 U.S.C. §103**

Claims 1, 3-13, and 16 are rejected under 35 U.S.C. 103(a), allegedly as being unpatentable over Mitsaides et. al. (XP-002293672) in view of Cohen et. al. (WO 02/053596) and Masferrer (PGPUB 20040127470) and Carosella et. al. (PGPUB 20040209296).

Applicants respectfully submit that a *prima facie* case of obviousness has not been made out because there was no motivation in the cited references directing one of ordinary skill to select the particular antibody 2.13.2 for treating the particular disorder multiple myeloma (MM).

The Examiner has acknowledged that the primary reference, Mitsaides et al., does not teach a method of administering the anti-IGF-1R antibody 2.13.2, the human genes, and the combination with various therapeutic agents. Applicants agree with the Examiner on these points. In fact, Mitsaides et al. only relates to a single particular neutralizing antibody, which is different from the antibody recited in the present application. Nonetheless, the Examiner alleges that the deficiencies are made up for by Cohen et al, Masferrer, and Corosella, to which Applicants respectfully disagree.

Applicants respectfully submit that it is known in the art that a vast number of distinct antibodies can be raised against a given antigen. Antibodies against the same antigen can differ

in a broad array of biological and pharmacological properties, such as amino acid sequences, selectivity, affinity, binding epitope, biological effects, and soon on. This is also true with antibodies against IGF-1R receptor, which is a very large protein molecule with multiple epitopes. While Cohen et al. disclose the antibody 2.13.2, they also disclose, generically or specifically, a large number of other antibodies that bind to IGF-1R. In addition, while Cohen et al teach a method of treating cancer generally and treating various specific types of cancer, treating MM is not specifically disclosed. There is nothing in Mitsaides et al. and/or Cohen et. al that leads to the selection of the particular antibody 2.13.2 from the vast number of possible IGF-1R antibodies for treating MM. The disclosure of Neither Masferrer and Carosella et al does not cure the deficiencies either because neither teaches the selection of antibody 2.13.2, nor does the Examiner allege that either of them does. For this reason alone, the claimed invention would not have been obvious.

Claims 1, 3-8 and 16 are also rejected under 35 U.S.C. §103(a) allegedly as being unpatentable over Mitsaides et. Al. (XP-002293672) in view of Emanuel et. Al. (PGPUB 20020151508) and Masferrer (PGPUB 20040127470) and Carosella et. Al. (PGPUB 20040209296). The Examiner reiterated the alleged disclosure of Mitsaides et. al, Masferrer, and Carosella et. el. With respect to Emanuel et. al, the Examiner alleges that they teach methods of treating cancers comprising administering a therapeutically effective amount of an antibody directed against the growth factor receptor associated with cancer. Applicants respectfully submit that these references do not render the claimed invention obvious at least for the following reasons.

Again, Applicants submit that there was no motivation in the cited references directing one of ordinary skill to select the particular antibody 2.13.2 for treating the particular disorder multiple myeloma. Applicants wish to reiterate the marks made above regarding the teaching of Mitsaides et. al, Masferrer, and Carosella et. el. Emanuel et al. mention only a general approach of treating cancers with an antibody against growth factor receptor. As Applicants have explained previously above, a vast number of distinct antibodies can be raised against a given antigen. Similarly, there are also a large number of different growth factor receptors and a large number of different types of cancers. The claimed invention is not drawn to the treatment of any

type of cancer with any antibody against any growth factor receptor; rather, it is drawn to the treatment of MM with the particular antibody 2.13.2 against the particular growth factor receptor IGF-1R. There is nothing in Emanuel et al, or any of the other cited references, that would lead a person of ordinary skill to the claimed invention. Accordingly, the claimed invention would not have been obvious over the cited references.

**VII. Concluding Remarks**

In view of the amendments and foregoing remarks, Applicants respectfully request reconsideration of the matter, the withdrawal of all the rejections, and timely issuance of a Notice of Allowance.

Respectfully submitted,

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